SEP 1 4 2005

K052345

*GE Healthcare*

# Advantage Sim MD
# 510 (k) Summary of Safety and Effectiveness

**This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)**

1. **Identification of submitter:**

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3000 N. Grandview Blvd
Waukesha, 53188
USA
Telephone: 262-544-3894
Fax: 262-548-4768
Date Prepared: May 10, 2005

2. **Identification of Product:**

| | |
|---|---|
| **Device name** | Advantage Sim MD. |
| **Classification name** | Radiation therapy simulation system per 21CFR Section 892 5840 |
| **Manufacturer/ Distributor** | General Electric Medical Systems<br>283, Rue de la Minière<br>78533 BUC Cedex France |

3. **Marketed Devices**

Advantage Sim MD is substantially equivalent to the devices listed below:

| | |
|---|---|
| Model: | Advantage Sim 6.0 |
| Manufacturer: | General Electric Medical Systems |
| 510 (k): | K021780 |
| Model: | Advantage 4D option |
| Manufacturer: | General Electric Medical Systems |
| 510 (k): | K032915 |
| Model: | Advantage Windows CT/PET Fusion |
| Manufacturer: | General Electric Medical Systems |
| 510 (k): | K010336 |

| | |
|---|---|
| Model: | Volume Viewer Plus |
| Manufacturer: | General Electric Medical Systems |
| 510 (k): | K041521 |

4. **Device Description :**

AdvantageSim MD is used to prepare geometric and anatomical data relating to a proposed external beam radiotherapy treatment prior to dosimetry planning. Anatomical volumes can be defined automatically or manually in three dimensions using a set of CT images acquired with the patient in the proposed treatment position. Definition of the anatomical volumes may be assisted by additional CT, MR, PET or SPECT studies that have been co-registered with the planning CT scan. Additionally, CT & PET data from a respiratory tracked examination may be used to allow the user define the target or treatment volume over a defined range of the respiratory cycle.
The geometric parameters of a proposed treatment field are selected to allow non-dosimetric, interactive optimization of field coverage. Defined anatomical structures and geometric treatments fields are displayed on transverse images, on reformatted sagittal, coronal or oblique images, on 3 D views created from the images, or on a beam eye's view display with or without the display of defined structures with or without the display of digitally reconstructed radiograph.

The GE Advantage Sim MD has to ensure relations with the following external systems:

**Data Export**
Image, volume and plan data are exported in accordance with DICOM V3.0 with all radiotherapy specific data included in a DICOM V3.0 object - including RT Plan and RTSS- Structure Set. Implementation profile is available on request. NOTE: Any treatment planning system connected to AdvantageSim MD must be DICOM 3.0 compatible and capable of reading the AdvantageSim MD radiotherapy DICOM V3.0 -including RT Plan and RTSS- object Structure Set. Export of treatment plan data to any external system, and its correct interpretation by that system must be fully validated before use.

**Marking Systems**
AdvantageSim MD stores isocenter coordinates and user defined marker coordinates onto an external accessible directory using a published protocol readable by external mobile laser controller. Currently supports Gammex and LAP formats.
Laser shifts sent to the external laser systems can be corrected for table deflection by identifying the fiducial landmark location within the image volume.

**RT Data Import**

Image, volume and plan data can be imported in accordance with the RT objects of the DICOM Standard. Import of treatment plan data from an external system, and its correct interpretation by AdvantageSim MD , must be validated before use.

**Hardcopy**

Hardcopy of all displays and plan data can be made at selected magnification on paper or transparency material. Users can print DRR to film at user defined SID if equipped with an Advantage WorkstationTM compatible Laser camera**, with the appropriate AW Laser Camera Interface. (AW Option). Hardcopy of beam parameters and of isocenter coordinates, using IEC standard, can be made on an optional Postscript printer

**Archiving**
AdvantageSim MD can save DICOM images and DICOM RT objects on single-session DICOM CD R using an optional CD ROM writer.

**Configuration Requirements**

AdvantageSim MD is compatible with Advantage Windows WorkstationTM 4.1 or higher

## 5. Indications for Use

Advantage Sim MD is used to prepare geometric and anatomical data relating to a proposed external beam radiotherapy treatment prior to dosimetry planning. Anatomical volumes can be defined automatically or manually in three dimensions using a set of CT images acquired with the patient in the proposed treatment position. Definition of the anatomical volumes may be assisted by additional CT, MR, PET or SPECT studies that have been co-registered with the planning CT scan. Additionally, CT & PET data from a respiratory tracked examination may be used to allow the user define the target or treatment volume over a defined range of the respiratory cycle.

The geometric parameters of a proposed treatment field are selected to allow non-dosimetric, interactive optimization of field coverage. Defined anatomical structures and geometric treatments fields are displayed on transverse images, on reformatted sagittal, coronal or oblique images, on 3 D views created from the images, or on a beam eye's view display with or without the display of defined structures with or without the display of digitally reconstructed radiograph

## 6. Comparison with Predicate Device

Advantage Sim MD, and all of its predicates are software options that operate on Advantage Workstation 4.2 (some predicates on 4.0 and 4.1 as well). The functional features of Advantage Sim MD software package are substantially equivalent to that of the following devices:

| Device Name | FDA Clearance Number |
|---|---|
| Advantage Sim 6.0 | K021780 |
| Advantage 4D option | K032915 |
| Advantage Windows CT/PET Fusion | K010336 |
| Volume Viewer Plus | K041521 |

7. **Adverse Effects on Health**

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

8. **Conclusions**

The Advantage Sim MD does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the Advantage Sim MD to be equivalent to those of Advantage Sim 6.0 (K021780), Advantage 4D option, Advantage Windows CT/PET Fusion (K010336) and Volume Viewer Plus (K041521).

# Third Party Review Quality Assessment

**Section 1 – Submission Information**

510(k) No.: K052341 Third Party Organization: Intertek

Third Party's Primary Reviewer(s): Deane

ODE/OIVD Division: DRAD Branch/Team: RDD

**Section 2 – 510(k) Decision**

Third party recommendation: SE ✓ NSE ___ Other (specify): ___

ODE/OIVD final decision: SE ✓ NSE ___ Other (specify): ___

**Section 3 – Assessment of Third Party Review**

| Review Element | Rating (check one) | | |
|---|---|---|---|
| | Adequate | Minor Issue(s) | Major Issue(s) |
| a. Determination of device eligibility for third party review | ✓ | | |
| b. Extent of pre-submission consultation with ODE/OIVD division | ✓ | | |
| c. Organization and format of review documentation | ✓ | | |
| d. Determination of 510(k) administrative completeness (screening review) | ✓ | | |
| e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission | ✓ | | |
| f. Comparison to legally marketed devices—identification and analysis of key similarities and differences | ✓ | | |
| g. Rationale for conclusions and recommendation | ✓ | | |
| h. Use of guidance documents and standards | ✓ | | |
| i. Resolution of 510(k) deficiencies and FDA requests for additional information | ✓ | | |
| j. Scope of reviewer expertise and use of consulting reviewers | ✓ | | |
| k. Other (specify): | | | |

Comments (explanation of ratings/issues): ___

**Section 4 – ODE/OIVD Assessor Information**

Assessed by: [signature] Date: 9/1/05 Tel. No.: ✓

**Routing:** Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2005

GE Healthcare
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K052345
Trade/Device Name: Advantage SIM MD
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: KPG
Dated: August 22, 2005
Received: August 26, 2005

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K052345

Device Name: **ADVANTAGE SIM MD**

Indications for Use:

AdvantageSim MD is used to prepare geometric and anatomical data relating to a proposed external beam radiotherapy treatment prior to dosimetry planning. Anatomical volumes can be defined automatically or manually in three dimensions using a set of CT images acquired with the patient in the proposed treatment position. Definition of the anatomical volumes may be assisted by additional CT, MR, PET or SPECT studies that have been co-registered with the planning CT scan. Additionally, CT & PET data from a respiratory tracked examination may be used to allow the user to define the target or treatment volume over a defined range of the respiratory cycle.

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052345